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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,876	10/26/2001	Darrell C. Conklin	97-63C1	8340

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EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/039,876	CONKLIN ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 22-31 and 34, drawn to polynucleotide encoding the polypeptide of SEQ ID NO:2, vector containing aid polynucleotide, cell containing said vector and method of producing the polypeptide, classified in class 435, subclass 69.1.

II. Claims 32-33, drawn to polypeptide of SEQ ID NO:2, classified in class 530, subclass 350.

III. Claims 35-37, drawn to antibody which specifically binds to the polypeptide of SEQ ID NO:2 and method of producing said polypeptide, classified in class 530, subclass 387.1.

IV. Claim 38, drawn to method of detecting the presence of an antagonist of z219a protein activity by adding the z219a polypeptide to a transfected, Z219a-responsive cell , in the presence and absence of a test sample, classified in class 435, subclass 7.8.

V. Claim 39, drawn to method of detecting the presence of an agonist of z219 a protein activity by adding test sample a transfected, Z219a-responsive cell, in the presence and absence of a test sample, classified in class 435, subclass 7.21.

VI. Claim 40, drawn to method for detecting a chromosome 21 trisomy or partial trisomy comprising hybridization to the polynucleotide of SEQ ID NO:1 or SEQ ID NO:8, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons.

Inventions I-III are patentably distinct products.

The polypeptide of group II and polynucleotide of group I are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. The information provided by the polynucleotide of group I could be used to make a materially different polypeptide than that of group II. For example, a nucleic acid which hybridizes to SEQ ID NO: 1, even under stringent conditions, encompasses molecules which contain point mutations, splice sites, frameshift mutations or stop codons which would result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common with SEQ ID NO. 2. In addition, while a polypeptide of group II can made by methods using some, but not all, of the polynucleotides that fall within the scope of group I, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups II and I are patentably distinct.

Furthermore, searching the inventions of groups II and I together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups II and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides, which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers, which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. In addition, the polypeptide claims include polypeptides having 70% identity to the sequence identified. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. The scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above; furthermore, a search of the nucleic acid molecules of claim 1(b) would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of group II. As such, it would be burdensome to search the inventions of groups II and I together.

The polypeptide of group II and the antibody of group III are patentably distinct for the following reasons:

While the inventions of both group II and group III are polypeptides, in this instance the polypeptide of group II is a single chain molecule that functions as an enzyme, whereas the polypeptide of group III encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group II and the antibody of group III are structurally distinct molecules; any relationship between a polypeptide of group II and an antibody of group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

In this case, the polypeptide of group II is a large molecule which contains potentially hundreds of regions to which an antibody may bind, whereas the antibody of group III is defined in terms of its binding specificity to a small structure within SEQ ID NO: 2. Thus immunization with the polypeptides of group II would result in the production of antibodies outside the scope of group III (i.e., antibodies that bind to regions other than residues 110-118 of SEQ ID NO: 2. Therefore the polypeptide and antibody are patentably distinct.

Furthermore, searching the inventions of group II and group III would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the

protein. However, such a search is not required to identify the antibodies of group III. Furthermore, antibodies which bind to an epitope of a polypeptide of group II may be known even if a polypeptide of group II is novel. The technical literature search for the polypeptide of group II and the antibody of group III are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The polynucleotide of group I and the antibody of group III are patentably distinct for the following reasons. The antibody of group III includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of group II which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group I will not encode an antibody of group III, and the antibody of group III cannot be encoded by a polynucleotide of group I. Therefore the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group I and group III would impose a serious search burden since a search of the

polynucleotide of group I is would not be used to determine the patentability of an antibody of group III, and vice-versa.

Inventions IV, V, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of method of detecting the presence of an antagonist of z219a protein (group IV), method of detecting the presence of an agonist of z219a protein (group V), and method for detecting a chromosome 21 trisomy or partial trisomy comprising hybridization to the polynucleotide of SEQ ID NO:1 or SEQ ID NO:8 (group VI) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary detecting a chromosome 21 trisomy or partial trisomy differ significantly for each of the materials. Group IV measures antagonist activity by adding test compound and Z219a polypeptide, the addition of Z21a polypeptide to test compound is not required for measuring agonist activity of Group V. Group VI is a hybridization technique used in neither Group IV or IV. Therefore, each method is divergent in materials and steps. For these reasons the Inventions IV, V and VI are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups IV, V and VI have a separate status in the art as

shown by their different classifications. As such, it would be burdensome to search the inventions of Groups IV, V and VI together.

Inventions of Group I and the methods of Groups IV, V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of group I can be used to make recombinant proteins as opposed to its use in detecting a chromosome 21 trisomy.

Searching the inventions of Groups I and IV-VI together would impose serious search burden. The inventions of Groups I , IV-VI have a separate status in the art as shown by their different classifications.

Inventions of Group II and the methods of Groups IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein can be used to produce antibodies. Searching the inventions of Groups II and IV-V together would impose serious search burden. The inventions of Groups II , IV-V have a separate status in the art as shown by their different classifications.

Inventions III and IV-Vi are unrelated because the product of group II is not used or otherwise involved in the process of group IV-VI.

Inventions II and VI are unrelated because the product of group II is not used or otherwise involved in the process of group IV-VI.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March

26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nirmal S. Basi
Art unit 1646
September 29,2004

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